

September 8, 2023

VIA ECF

Honorable Edward S. Kiel, U.S.M.J.
United States District Court, District of New Jersey
United States Post Office & Courthouse
Federal Square, Courtroom 8
Newark, New Jersey 07101

**Re: Joint Status Conference Letter
U.S. ex rel Silbersher v. Janssen Biotech Inc.
Civil Action No. 19-12107(KM-ESK)**

Dear Judge Kiel:

Counsel for the parties in the above-referenced matter respectfully submit this joint letter to advise the Court of the status of discovery in this matter in advance of the September 12, 2023 status conference.

I. Party Discovery

A. *Relator's Discovery Requests and Defendants' Responses*

Relator's Statement

On July 18, 2023, the parties appeared before the Court for a status conference, during which the Court stated that Defendants should provide a privilege log, particularly with respect to Defendants' purported diligence prior to making the Commercial Success Argument to the Patent Office. (Tr. 14, 15) In doing so, the Court noted that the underlying information that patent counsel relied upon in determining that they had a good faith basis to make the Commercial Success Argument was "relevant and should be provided." (Tr. 11, 12, 15) The Court also said that Defendants should continue making a rolling production of the ANDA Litigation documents and that all documents that do not involve the confidential information of the last objecting generic manufacturer—Mylan—be produced "soon." (Tr. 20)

Having received no additional documents or other responsive discovery from Defendants, Relator sent on August 24, 2023, a deficiency letter requesting to meet and confer about: (i) the privilege log the Court had ordered Defendants to produce; (ii) Defendants' deficient interrogatory responses, particularly with respect to patent prosecution counsel's diligence relating to the Commercial Success Argument; (iii) Defendants' continued withholding of ANDA Litigation documents; and (iv) the fact that many ANDA Litigation deposition transcripts were missing, and that most of those that were produced were not paired with their relevant exhibits.

Additionally, and pursuant to the Court's suggestion at the July 18 status conference, Relator also offered to produce his non-public intellectual property opinions for Markman

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Advisors, LLC's clients or potential clients generally discussing inequitable conduct, commercial success, and antitrust theories of liability for misconduct before the Patent Office. Defendants later that day then produced 24 additional ANDA Litigation documents they had previously withheld, but Defendants did not otherwise respond to Relator's deficiency letter or Relator's request to meet and confer.

Because Defendants did not respond substantively to Relator's deficiency letter,¹ Relator sent a follow-up deficiency letter on September 1, 2023, again requesting Defendants to supplement their responses to specific interrogatories, particularly with respect to any diligence relating to the Commercial Success Argument that Defendants submitted to the Patent Office. Relator also informed Defendants that Mylan had agreed to review any ANDA Litigation documents that Defendants claim to be withholding based on purported confidentiality issues, and requested Defendants to identify and provide those documents to Mylan as soon as possible.

On September 5, 2023, Defendants provided an answer to Relator's meet and confer request, and the parties conferred the following day. During the September 6 meeting, Defendants stated that due to events outside of their control, they would be unable to provide additional information until late September, at the earliest. Relator sought to confirm that Defendants had no substantive dispute with Relator's request that Defendants supplement their interrogatory answers, as set forth in Relator's August 24 and September 1 deficiency letters. Defendants did not provide any substantive objection, but instead suggested that one interrogatory—Interrogatory 9, which asked Defendants to please “identify the date and participants of all meetings, interviews, or discussions where the Commercial Success Argument was discussed or analyzed”—was perhaps too overbroad, because the participants may not be able to remember all of them. Relator then replied that Defendants should then identify those meetings they do remember, or which are otherwise documented.

In light of the circumstances relating to the delay in supplementing Defendants' interrogatory responses, Relator agrees to wait until October 6, 2023 to receive Defendants' supplemental interrogatory answers, provided that Defendants provide full and complete answers as specified in Relator's August 24 and September 1 deficiency letters. This is appropriate because Defendants provided no substantive objections during the parties' meet and confer discussions.

Defendants did address the issue raised by Relator concerning the apparent lack of deposition transcripts paired with the corresponding exhibits introduced at those depositions. For example, Relator noted in his August 24 letter that although there “were 49 deposition notices for the ANDA Litigation,” “only 17 deposition transcripts have been produced” and that “many exhibits appear to be missing (or lack metadata necessary to locate and identify them).” In

¹ Defendants did call counsel and request an adjournment of the status conference. Relator agreed to continue the hearing date, without any conditions, if the reason for the requested adjournment was that the “date [was] inconvenient to any attorney who would like to attend.” Relator also offered that, if on the other hand, “the reason defendants are requesting adjournment is because they have not yet made material progress on what the court ordered them to do last time,” “then Relator would agree to an adjournment” “provided that defendants commit to providing at least some outstanding discovery within a reasonable time.”

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response, Defendants say that they produced files from the ANDA Litigation as they exist, and that they “do not have an obligation to create metadata” that would allow Relator to pair deposition transcripts with their related exhibits. Relator believes that surely, deposition transcripts are kept with their exhibits in Defendants’ files and should be produced that way.

Therefore, unless this issue is resolved—and Defendants produce a complete set of deposition transcripts together with their exhibits, and either (i) provide metadata to allow for document family grouping so that the exhibits can be paired with their respective transcripts, or (ii) identify the correct exhibits used at the relevant depositions—then Relator intends to seek court intervention. Simply put, Relator is entitled to all the depositions from the underlying ANDA Litigations, along with the corresponding exhibits used at each deposition.

Finally, although Relator is awaiting Defendants’ supplemental interrogatory answers before identifying additional document custodians whose files should be searched, Relator has confirmed that at a minimum, Relator will request for the custodial files of Joaquin Duato, the current Chief Executive Officer of Johnson & Johnson (and in 2011 the Executive Vice President, Worldwide Chairman, Pharmaceuticals); and Robert Bazemore (at the time, the President of Janssen Biotech, Inc. in charge of the Zytiga launch in 2011).

Defendants’ Statement

On February 28, 2023, Defendants substantially completed their document production in response to Relator’s First Set of Requests for Production (“RFPs”). Since then, Defendants have also completed their data production in response to Relator’s First Set of RFPs and have produced additional documents from the underlying patent infringement litigation including additional materials from consenting generic-drug manufacturers. To date, Defendants have made, on a rolling basis beginning in September 2022, a total of eighteen productions since the parties’ August 17, 2022 meet-and-confer. These eighteen productions comprise 49,996 documents and a total of 804,626 pages. Previously, Defendants produced 78,729 documents that were produced during the course of, or originated from, the prior ANDA Litigations, totaling 5,404,397 pages.

On May 5, 2023, Relator served a Second Set of RFPs and First Set of Interrogatories. Defendants served Responses and Objections to these requests and interrogatories on June 5, 2023. Defendants’ review and production in response to Relator’s Second Set of RFPs remain ongoing, but Defendants note that much of the material sought by Relator’s Second Set of RFPs was previously requested and produced or is protected from disclosure on grounds of privilege. Defendants expect to make a complete production of non-privileged material responsive to Relator’s Second RFPs and provide a privilege log prior to the September 12 status conference.

Defendants have also continued to move forward with a number of items discussed at the July 18, 2023 status conference. In particular, Defendants made a production of ANDA litigation material identified on its face as not implicating the confidential information of the remaining non-consenting generic manufacturer on August 24, 2023. Defendants are preparing an index of the remaining ANDA litigation material withheld for confidentiality for review by Mylan. Defendants understand that Mylan will review the index and any withheld material to identify those documents that it does not believe implicate its confidentiality. Defendants will produce any such material to

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Relator.

Defendants are also continuing to work on supplementing their responses to several of Relator's interrogatories, most notably those relating to the "commercial success" argument advanced in support of the '340 patent application. As Relator knows, the employee most directly responsible for prosecuting that application was an in-house counsel. Preparing the supplemental responses Relator has demanded therefore requires reviewing a significant volume of documents, navigating various privilege issues, and then meeting with that individual to probe their recollections. For various reasons beyond our control, most notably a surgical procedure for a critical witness, Defendants have been unable to complete that process in advance of the September 12 conference. Defendants are now scheduled to meet with that witness on September 28 and will provide Relator with revised interrogatory responses thereafter.

Defendants apprised Relator's counsel of these circumstances and proposed to adjourn the status conference until October to accommodate the witness's surgery and preserve the Court's time and resources, ensuring that any outstanding issues related to these interrogatory responses were properly teed up for the Court's consideration. Relator's counsel refused to consent to any adjournment without multiple new concessions from Defendants.

On September 6, the parties met and conferred regarding issues raised in Relator's August 24 letter to Defendants, including the timing of Defendants' revised interrogatory responses. Relator's counsel's statement that Defendants provided no response to the August 24 letter until the day prior to the meet-and-confer is not accurate.² During the meet-and-confer, after Defendants explained once more that the surgery of a witness left Defendants' unable to provide revised responses until the beginning of October, Relator agreed to that proposal. Relator continued to press for additional objections to those requests, and Defendants informed him that they would not be in a position to fully respond until they have spoken with the witness. Defendants, however,

² On Tuesday, August 29, 2023, Defendants contacted counsel for Relator by telephone to acknowledge the August 24 letter, inform them of the circumstances surrounding Defendants' witness's surgery, and to propose an adjournment of the status conference.

Relator's counsel responded after business hours on Friday, September 1, and refused to consent to adjourning the status conference without other concessions

The next business day, Tuesday September 5, Defendants informed Relator's counsel that, given Relator's unwillingness to provide an extension to accommodate the witness's surgery, Defendants were prepared to proceed with the status conference as scheduled. Defendants also agreed to meet and confer on several issues the following day. That same day, Tuesday, September 5, Defendants provided Relator's counsel with both a written response to Relator's August 24 letter as well as a draft joint submission to this Court in advance of the September 12 status conference.

Relator's counsel did not provide proposed revisions to this draft joint submission until the afternoon of the date that it was due. Although Defendants have endeavored to provide this Court with a true joint submission, the extent of Relator's edits necessitated the parties' submission of distinct positions.

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did not concede the propriety of Defendants' requests, and offered him an example of an interrogatory that is facially overbroad on the spot.

B. *Defendants' Discovery Requests and Relator's Responses*

Defendants' Statement

Relator, for his part, has responded to Defendants' first and second set of Requests for Production ("RFPs") and Defendants' first and second set of Interrogatories, producing a total of 113 documents comprising 3,451 pages.

On August 24, 2023, Relator complied with this Court's April 10, 2023 Order, ECF 246, as clarified during the July 18, 2023 status conference, and provided Defendants with a privilege log containing Relator's privileged communications regarding his pre-filing investigation. Relator's log spans the year predating the filing of his Complaint and contains 82 entries. This log supplemented Relator's prior productions of non-privileged documents and links contained in these communication files.

After an initial review of Relator's log, Defendants have identified several entries supported by dubious claims of privilege. In particular, Relator has withheld his communications with his law firm partners as privileged. Although Defendants do not doubt these individuals are attorneys, that alone does not suffice to shield a communication as privileged. Defendants expect to provide Relator with a deficiency letter in the coming weeks and to engage in meet-and-confers regarding these documents; however, this Court's intervention may be necessary regarding the propriety of these privilege designations.

In conjunction with providing Defendants with his privilege log, Relator has indicated that he intends to preserve his right to testify as a fact witness. Accordingly, Relator has committed to producing "non-public prior written work product, to the extent they exist, for clients of Markman Advisors, LLC concerning commercial success and inequitable conduct." Relator, however, has requested that the parties meet and confer regarding steps to address confidentiality considerations, including the redaction of Markman Advisors' client names.

Although Defendants see this as a positive step, they continue to contest the propriety of Relator's testimony as a fact witness. Moreover, Defendants note that Relator's commitment is narrower than what Defendants requested in their Request for Production 26, which sought documents provided to clients or *potential* clients related to "(a) fraud or inequitable conduct in a patent prosecution; (b) the effect and/or propriety of obtaining multiple patents on a single brand name drug; (c) the use or application of a "commercial success" argument to procure a patent; and/or (d) theories of liability for conduct before the USPTO." Defendants thus have sought to clarify whether Relator intends to fully comply with RFP 26, or whether he intends to produce only a self-selected subset of material responsive to that request. Moreover, because Relator seeks to preserve his right to testify as to his "intellectual property background" and "how he identified the '438 patent as being fraudulently obtained," Defendants expect to serve additional document discovery to probe these particular topics and to readvance earlier requests related to these issues.

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Defendants also previously served nineteen interrogatories on Relator; however, upon review, Defendants have identified answers to at least eleven that are plainly deficient. Rather than provide satisfactory responses, Relator simply refers Defendants to his Second Amended Complaint in response to many of Defendants' requests. For example, Defendants have requested that Relator describe with particularity the "independent investigation" that caused him to believe that Defendants withheld information from the USPTO; however, Relator fails to offer any meaningful response beyond citing to paragraphs in the Complaint that describe his allegations about *Defendants*' purported conduct. These scattered cites, however, say nothing about the investigative steps that *Relator* took to uncover the purported fraud. Given Relator's recent representations that he will testify as a fact witness, Defendants intend to meet and confer with Relator regarding the adequacy of these responses and, if necessary, seek this Court's intervention to compel sufficient answers.

Relator's Statement

Defendants apparently intend to challenge several entries in Relator's privilege log. In particular, Relator consulted with Gaston Kroub and Sergey Kolmykov—two intellectual property lawyers with specific expertise in pharmaceutical patents, and who are also his law partners—concerning intellectual property issues pertinent to this case with the understanding that Messrs. Kroub and Kolmykov would periodically act as his counsel on specialized intellectual property matters in this action. Relator therefore has claimed privilege over such communications.

Relator has notified the Court and Defendants on several occasions that he intends to preserve his right to testify as a fact witness, particularly with respect to his intellectual property background and pre-filing investigation of this action. These topics include, without limitation, how Relator identified the '438 patent as having been fraudulently obtained, and the reasons supporting his determinations. Accordingly, Relator has offered to produce non-public prior written work product, to the extent they exist, for clients or potential clients of Markman Advisors, LLC concerning inequitable conduct, commercial success, and antitrust theories of liability for misconduct before the Patent Office after redacting any client or potential client information, including, without limitation, the client or potential client's identity.

Defendants have also asked Relator to produce documents reflecting his non-public opinions relating to the effect or propriety of obtaining multiple patents on a single brand name drug. Relator believes that this topic overreaches, because Relator has not alleged patent misconduct relating to "patent thickets," or the obtaining of multiple patents on a single brand name drug. Therefore, this particular intellectual property issue is not relevant to this case.

II. Government Discovery

As the parties previously reported, Defendants have served subpoenas duces tecum on (1) the United States Patent and Trademark Office, (2) the United States Department of Veterans Affairs ("VA"), and (3) the Centers for Medicare and Medicaid Services ("CMS"). Defendants continue to discuss the subpoenas with the United States Patent and Trademark Office ("USPTO") and the Centers for Medicare and Medicaid Services. Defendants anticipate they may need to file an action against USPTO to enforce the subpoena, which per Rule 45, would need to be within

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100 miles of the USPTO's place of business.

On September 7, 2023, Relator issued for service separate subpoenas on the VA and CMS, seeking information in addition to what the government has already produced in response to Defendants' subpoenas (pending return of service confirmation).

III. Other Issues

The parties agree that no issues other than those described above need be addressed at this time.

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Respectfully yours,

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